

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Confirmation No.: 6852

Kirkor Sirinyan

Application No.: 10/613,819

Group Art Unit: 1623

Filing Date: July 3, 2003

Examiner: Elli Peselev

For: Endoparasitocidal and Ectoparasitocidal Agents

Mail Stop Appeal-Brief Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

**APPELLANT'S REPLY BRIEF
PURSUANT TO 37 C.F.R. § 41.41**

Appellant submits this Reply Brief in response to the Examiner's Answer dated August 9, 2010 in connection with the above-identified application. This reply is being filed within two months of said Answer.

I. STATUS OF CLAIMS

Pending: Claims 11-24

Withdrawn: None

Allowed: None

Rejected: Claims 11-24

Canceled: None

Appealed: Claims 11-24

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- Claims 11-24 as allegedly being obvious over U.S. Pat. No. 5,712,295 to Mencke et al. (“the U.S. Mencke patent”) in view of U.S. Pat. No. 4,199,569 to Chabala, et al. (“the Chabala patent”).

III. ARGUMENTS

Appellants acknowledge the Examiner's withdrawal of the rejection of claims 11-24 for alleged obviousness over U.S. Pat. No. 5,712,295 to Mencke et al. ("the U.S. Mencke patent") in view of WO 96/38165 to Mencke et al. ("the Mencke publication")

With regard to the remaining rejection for alleged obviousness, the Examiner errs in the Answer brief by failing to identify any evidence indicating that those of ordinary skill would have been motivated to combine the teachings of the cited prior art in a way that would have produced the claimed invention.

The Examiner's Answer brief contends that it would have been obvious to combine the respective medicaments of the Mencke patent and the Chabala patent into a single composition because a person of ordinary skill in the art, if "presented with an animal having both an endoparasitic and an ectoparasitic infection" would have recognized that the treatment of the animal with only one of the respective medicaments would not be effective, and that treatment of both types of infections requires administration of both medicaments (*see* Examiner's Answer, paragraph bridging pages 5 and 6). However, even if the objective were to treat both types of infections in a single animal, it is already known among those skilled in the art that this objective can be attained by means *other than* the administration of a single composition that comprises both medicaments, and thus there is no motivation to experiment with the particular treatment developed by Appellants here.

Indeed, at the time the present application was filed, it was customary to protect pets against *both* endoparasites and ectoparasites by providing parenteral or oral treatment against the former and dermal treatment against the latter (*see* present application at page 2, lines 16-19). This practice demonstrates that it *was* known to treat both endoparasites and ectoparasites in the same animal. But, contrary to the Examiner's allegation, when a person of ordinary skill in the art was "presented with an animal having both an endoparasitic and an ectoparasitic infection," that person would have followed the conventional treatment of using *two different* treatment types: one via oral or parenteral administration (for endoparasites) and one via dermal administration (for ectoparasites). There is no teaching or suggestion in the cited references that one could – or should even try to – modify the approach of using two different treatment types by treating both parasites at once using a *single* composition in a *single* treatment type (*e.g.*,

dermal administration only or oral administration only). Indeed, the present application discloses the first-ever method for treating both endoparasites and ectoparasites using a *single* treatment modality.¹

The Examiner essentially argues that a person of ordinary skill in the art “could have” combined the relevant components of the Mencke patent and the Chabala patent into a single composition. But “could have” is legally insufficient to establish obviousness. *Ex parte Levensgood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (a statement that modifications of the prior art to meet the claimed invention would have been “well within the ordinary skill of the art at the time the claimed invention was made” because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references). Thus, the Examiner fails here as well to establish a *prima facie* of obviousness from the disclosures of the Mencke and Chabala patents.

The Examiner also relies on the fact that each reference discloses that oral administration is one possible way to deliver that reference’s an active ingredient. From this, the Examiner argues that a person of ordinary skill in the art would have been motivated to deliver the medicinals of the Mencke patent *and* those of the Chabala patent by oral administration. However, this allegation is insufficient to demonstrate the obviousness of the present claims in at least two respects.

First, the Examiner does not identify any evidence that either of the cited references, or any other reference or known logic, would influence a person of ordinary skill in the art to choose *oral* administration above the various other modes that are disclosed in the respective references. For example, even assuming a skilled artisan’s objective were to treat an animal that is infected with both endoparasites and ectoparasites with compounds from Mencke and Chabala, and even if that artisan selected to administer the Chabala compounds orally, the artisan is still faced with choosing among the many modes of administration taught by the Mencke patent for the Mencke compounds, which include enteral, parenteral, dermal, nasal, “by

¹ The Examiner states that “[n]one of the claims are limited to any type of administration”, which, while true, overlooks that although no particular mode of administration is required by the present claims, the recited methods include the administration of a single composition comprising the recited first and second ingredients, which in turn implicitly necessitates the delivery of both ingredients at once via a single mode of administration.

environment treatment”, or “with the aid of active-compound-containing shaped articles” (*see* Mencke patent at col. 7, lines 43-47). And this does not account for the fact that the Chabala patent, in the first instance, discloses numerous *different kinds* of oral administration. *See, e.g.*, col. 6, line 63 to col. 8, line 38.

The Examiner does not identify any evidence that a person of ordinary skill in the art would select an *oral* form of the Mencke patent’s disclosed enteral administration, or even the *same kind* of oral administration as that which might have been chosen to administer the compounds of the Chabala patent.² The Examiner’s argument that one of ordinary skill in the art would select the same kind of oral administration for delivery of both the Chabala compounds and the Mencke compounds is an unsupported conclusion. Such conclusory statements cannot provide the basis for a proper *prima facie* case of obviousness. *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (“rejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.”); *see also KSR Int’l. Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007) (quoting Federal Circuit statement with approval).

The Examiner’s obviousness conclusion fails in an additional respect. Even *if* one of ordinary skill would choose the same kind of administration modality for *both* the compounds of the Chabala patent as well as the compounds of the Mencke patent, there is still no suggestion that the respective compounds be combined *in the same composition*. For example, the Chabala patent provides that the disclosed compounds can be administered “in a dry, solid dosage form” (*see* col. 7, lines 9-10), and the Mencke patent discloses that its compounds can be administered in “solid preparations” (*see* col. 8, line 1). Thus, an animal infected with both ectoparasites and endoparasites can be treated by administering a first solid dosage form of a Chabala compound and by separately administering a second solid dosage form of a Mencke compound. There is no evidence that it would have been obvious to administer the respective compounds together in a single dosage form. It is the examiner’s burden to present some evidentiary basis for a claim rejection; a rejection is not properly founded on the examiner’s mere say-so that the references “could have” been modified or combined as posited. Indeed, the “could have” standard of

² The Chabala patent discloses numerous different kinds of oral administration. *See, e.g.*, col. 6, line 63 to col. 8, line 38.

obviousness is an improper one. *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984) (“[t]he mere fact a prior art reference could have been modified does not make the modification obvious unless the prior art suggested the desirability of the modification.”). Although it is true that, since *Gordon*, it has been held that the suggestion for modification need not come from the prior art itself, the suggestion or motivation must nonetheless come from somewhere, and somewhere other than an Examiner’s bare assertion. Because there is no evidence here of a valid source for any such suggestion, the rejection should be reversed.

The Examiner’s Reply does not provide a proper basis for the pending rejection in any respect. The rejection should be reversed.

Respectfully submitted,

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